Remarks

The Office action mailed June 12, 2007, has been reviewed and carefully considered. The specification has been amended to correct inadvertent errors.

Specification

A replacement Sequence Listing that now includes SEQ. ID. NO: 31 is hereby submitted.

35 U.S.C. §112, second paragraph, Rejection

Claims 26-28, 36, 38, 41-46 and 55-59 have been rejected under 35 U.S.C. §112, second paragraph. The examiner asserts that the claims are missing "steps for the method." However, these claims are not method claims; they are article of manufacture claims. The claims are directed to an immunoassay, and recite certain physical components of the immunoassay itself. In particular, claim 26 recites a first substrate to which is bound a multiple antigenic peptide (MAP) and a second substrate to which is bound another MAP. The substrates, for example, may be solid phase substrates as described at page 15, line 23 – page 16, line 19, of the present specification. Accordingly, it is clear from the claim language itself that claim 26 is not directed to a method for using an immunoassay. Moreover, the January 31, 2007, restriction requirement recognized that claim 26 was "drawn to a composition comprising at least two multiple antigenic peptides."

35 U.S.C. §103 Rejections

Claims 26-29, 38, 44-45, 55, 57, and 59 have been rejected for alleged obviousness over Simon et al. combined with Tam and Bridon et al. This rejection is traversed for the reasons set forth below.

The examiner recognizes that Simon et al. does not teach multiple antigenic peptides (MAP) or peptide sequences of less than 16 amino acid residues. The importance of these two features is explained in the present specification at page 15, lines 6-17:

> "The specificity of peptides generally tends to increase as the length of the peptides decreases, but shorter peptides may also have reduced reactivity, which can reduce the sensitivity of the test. The MAP structure can compensate for this reduced sensitivity. In particular, the plurality of shorter linear peptides in the presently disclosed MAPs enables optimization for specificity and sensitivity. The specificity is enhanced by shorter linear peptide portions that are more antigenicity focused. The sensitivity is enhanced by the plurality of shorter linear peptides. For instance, the analytical discernability of the assay results is increased (e.g., the optical density readout exhibits a more intense color). Although not bound by any theory, it is believed that since only a portion of the MAP molecule is in contact with the solid phase substrate, the other portions of the MAP molecule are free for antibody binding. In addition, MAPs provide increased antigen density, and thus an increased number of antibody binding sites per unit surface area."

Page 12, line 34 – page 13, line 1 of the specification also teaches that "[g]iven that longer peptides may give rise to non-specific reactivities outside or within primate lentiviruses, especially useful peptide sequences for MAP synthesis and assaying have less than about 16 amino acid residues per linear portion of each MAP." In summary, linear peptides as described in Simon et al. are not sufficiently sensitive. The longer sequences mean that a broader range of antibodies could react and it includes extraneous residues that are not critical for detection and/or differentiation.

Tam and Bridon et al. are relied upon by the examiner for teaching that it would have been obvious to modify Simon et al. to include a MAP format and antigenic sequences with less than 16 amino acid residues. However, as explained below in more detail, the teachings of Tam and Bridon et al are so far removed from an immunoassay for detecting primate immunodeficiency virus (PIV), that a person of ordinary skill in the art starting with the Simon et al. approach would not have consulted either Tam or Bridon et al. Tam or Bridon et al, in

particular, would hot have provided any reason for utilizing shorter amino acid sequences in the Simon et al. immunoassay.

Tam discloses several MAP constructs using various antigenic peptides (see Table I). However, none of the antigenic peptides are present in, derived from, or related to, a primate immunodeficiency virus. Moreover, Tam explored utilizing the MAP constructs for vaccines. There is no mention in Tam that MAP constructs could be utilized for diagnostic purposes, much less an enzyme immunoassay. Vaccines and immunoassays are quite different; one is therapeutic; the other is diagnostic. A person of ordinary skill in the art could not have reasonably predicted that an approach taken for a vaccine could be successfully applied in an immunoassay. The lack of connection to Simon et al. or the presently claimed immunoassay is especially apparent from the Tam's utter failure to even mention a PIV sequence or any applicability to PIV in general.

Although the sequences listed in Table 1 of Tam et al include less than 16 amino acid residues, there is nothing in Tam attributing any significance to the specific length of the sequences. In other words, it is simply coincidence that the sequences of Tam are less than 16 amino acid residues long. Coincidence, of course, is an insufficient reason to find that it would have been obvious to combine references.

Bridon et al. discloses a specific sub-genus of HIV-1 peptides. The peptides can be used in immunoassays for detecting HIV antibody in a test sample. However, Bridon et al. does not mention MAP constructs, the use of the HIV-1 peptides in an immunoassay for detecting SIV, or an immunoassay that includes both a detection component and a differentiation component. More importantly, Bridon et al. fails to mention any unique advantage associated with an amino acid sequence of less than 16 amino acids. Thus, there would have been no reason to employ the HIV-1 peptides of Bridon et al. in the MAP construct of Tam, much less the immunoassay of Simon et al.

The Office action on page 4 indicates that Bridon et al. teaches "captur[ing] a large number of SIV isolates." However, a review of Bridon et al. did not locate any reference to SIV

(and the Office action did not cite to any specific passage in Bridon et al.). Bridon et al is directed to detecting the presence of HIV-1 subtype O. Thus, the asserted factual basis for combining Bridon et al. with Tam and Simon et al. does not actually exist.

Dependent claims 36, 41-43, 46, 56 and 58 also have been rejected for alleged obviousness in view of the three above-discussed references further combined with Silvera et al, Hirsch et al., and Tsujimoto et al. These secondary references are simply relied upon for allegedly disclosing the features in the rejected dependent claims, and thus do not ameliorate the fatal flaw in the base rejection of independent claim 26. Since the obviousness rejection of claim 26 must be withdrawn, all claims that depend therefrom are also allowable.

It is respectfully submitted that the application is in condition for allowance. Should there be any questions regarding this application, examiner Snyder is invited to contact the undersigned attorney at the telephone number shown below.

Respectfully submitted,

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